UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,161	03/30/2001	Michael Detmar	MGH 1512 CIP	6294

20999 7590 03/26/2003

FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/26/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/822,161	DETMAR ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2002 and 04 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *8-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 16-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9, 12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

DETAILED ACTION

Amendment, response, and declaration filed on 11-25-02, 11-27-02 have been received and entered. New claims 16-29 have bee entered.

Election/Restrictions

Claims 8-15 **remain withdrawn** from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Prosecution history indicates that the Office has not addressed applicant's traversal in Paper No. 7 filed on 6-04-2002 regarding the restriction requirement. The traversal is on the ground(s) that the withdrawn claims 8-15 belonging to group II are products being used in the elected method group I. This is not found persuasive because MPEP 821.04 says that if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim is rejoined, ***NOT vice versa***. Applicant further argues that restriction is improper based on MPEP 808.02 and further argues that search of both groups do not put undue burden on the Office. These argument are not convincing because MPEP 808.02 says restriction is improper if the claims are not patentably distinct and the Office provided applicant why the two groups are patentably distinct (see Paper No. 4) and also because the elected claims are drawn to method of treating difficult diseases, not just using the cell-matrix structure as applicant argues but using various other active ingredients. The cell-matrix structure is just the hardware that houses other active ingredients called anti-antigenic molecule that is really being used for the treatment. These inventions are distinct for the reasons given (Paper No. 4). The search required for each of the inventions is not coextensive with regard to the literature. Further, a reference which would anticipate

the invention of any one group would not necessarily anticipate or make obvious the any of the other group. For these reasons, restriction for examination purposes is proper. Applicant further argues restriction requirement would result in inefficiencies and unnecessary expenditure by both the Applicants and PTO, as well as extreme prejudice to applicants in view of GATT. These arguments are not persuasive either because inefficiencies and unnecessary expenditure could be avoided by careful drafting of claims in that they contain applicant's true single invention as precise as possible, not claiming multiple inventions in a single application.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 8-15 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-29 are pending and claims 1-7, and 16-29 are examined on merits.

Oath/Declaration

The new oath or declaration correcting the objected defect has been received, therefore the objection is withdrawn.

Specification

The objection of the specification is withdrawn in view of amendment.

Priority

The prosecution history indicates that the Office denied applicant's claim for domestic priority to the provisional application No. 60/127,221 under 35 U.S.C. 119(e) because the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-7 of this application. Applicant argues that the provisional application at pages 5 and 18 disclose method of using genetically modified cell that express TSP-2 and further argues that the provisional application discloses "a slow release matrix" at page 39 line 7. However, these arguments are not persuasive because instant invention is drawn to method using cell-

matrix structure comprising a matrix having attached thereto cells stably expressing a gene encoding an anti-angiogenic molecule. The specification at page 39 line 7 says "gene therapy construct ---can comprise a slow release matrix" indicating the gene therapy construct is in the matrix. Further, the provisional application does not disclose the information disclosed at 20-23 in the instant specification about how to make the matrix used in the instant claim. Therefore, the Office maintains denial of domestic priority to the provisional application No. 60/127,221 under 35 U.S.C. 119(e).

Claim Rejections - 35 USC § 112

Claims 1-7 **remain rejected** for reason of record and the new claims 16-29 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of tumor using cell matrix structure comprises a matrix having attached thereto cells expressing TSP-2, does not reasonably provide enablement for any other anti-angiogenic molecule for tumor or any other diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to **use** the invention commensurate in scope with these claims. Applicant argues that it does not require undue experiment to practice the full scope of the invention because the amount of direction or guidance presented is high, working examples are present. This argument is not persuasive because the amount of direction or guidance in the instant specification is only directed to method of treating tumor using cell matrix structure comprises a matrix having attached thereto cells expressing TSP-2 (note Figures 2 and 3). Applicant further argues that the prior art is replete with references characterizing the structure and activity of anti-angiogenic molecules, the relative skill of those in the art is high, and the predictability of the art is also high. These arguments are persuasive either because the arguments are not commensurate in scope with the instant claims drawn to method of treating the most difficult diseases to be treated (note the instant claim 2) with the molecules still being investigated for possible therapeutic agents. Note the instant claims are not drawn to anti-angiogenic molecules per se. The relative skill in the art for treating the diseases listed in claim 2 is not high and the art recognizes most of the

diseases listed in instant claim 2 are not easy to treat. Note for example, Cherrington et el (IDS, 2000, Advances in Cancer Research vol. 79, pages 38). The art recognized cancer or multiple sclerosis treatment is unpredictable. Given the relevant factors in Wands, the Office maintains it requires undue experimentation to practice the full scope of the claimed invention.

NEW GROUNDS OF REJECTION

Double Patenting

Claim 26 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 6. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

Claims 27-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention. The support for the specific species listed in the claims as belonging to the generic molecule of claim 1 as applicant's invention at the time the application was filed, is not apparent to the Office. Applicant is requested to point out the support in the originally filed specification.

Conclusion

Applicant's amendment and Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 11-29-2000 necessitated the new ground(s) of rejection presented in this Office action. prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). . See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
March 20, 2003

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600